OPDP Submissions: Current Process and What's Ahead

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- Office of Prescription Drug Promotion (OPDP) (Formerly the Division of Drug Marketing, Advertising, and Communications - DDMAC) Organizational Structure
- Overview of OPDP and Regulation of Prescription Drug Promotion
- Current Submission Process
- Electronic Submissions Working Group progress
- Draft Module 1 Update
- What's Ahead

Office of Prescription Drug Promotion

OPDP

- Senior Managers
  - Thomas Abrams
  - Mark Askine
  - Marci Kiester
  - Robert Dean
  - Catherine Gray

- Management Team
  - Team Leaders and Senior Managers working together to implement this.

- OPDP alignment based on functional areas
  - Review functions
  - Policy and support functions

Office of Prescription Drug Promotion

- Immediate Office
- Division of Professional Promotion
  - Division Director
    - 4 Review Teams and Team Leaders
- Division of DTC Promotion
  - Division Director
    - 4 Review Teams and Team Leaders

Office of Prescription Drug Promotion

- OPDP Director
  - Associate Office Director (Review Functions)
  - Associate Office Director (Policy and Support Functions)
- Associate Office Director (Review Functions)
  - Division of Professional Promotion
  - Division of DTC Promotion
- Associate Office Director (Policy and Support Functions)
  - Regulatory Counsel Team and Team Leader
  - Social Science Research Team

    Project Management Team

MISSION

- To protect the public health by assuring balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.

Regulatory Authority

- Federal Food, Drug and Cosmetic Act
  - Prescription drug promotion **must**...
    - Not be false or misleading
    - Have fair balance
    - Be consistent with the approved product labeling, or the package insert (PI)
    - Only include claims substantiated by adequate and well-controlled clinical studies

Regulatory Authority

- **Code of Federal Regulations (CFR)**
  - **202.1 - Prescription Drug Advertising**
  - **312.7 - Preapproval Promotion**
  - **314.550 - Subpart H, Accelerated Approval for Drugs**
  - **601.40 - Subpart E, Accelerated Approval for Biologics**

Regulatory Authority

- Post-Approval Regulations located in 21 CFR 314.81(b)(3):
  - Require the submission of all promotional materials at the time of initial dissemination or publication
  - Must include Form FDA 2253 and current PI
  - OPDP receives >80K submissions per year
  - OPDP does not generally “pre-clear” promotional materials

Advice to Industry

- Provide comments on DRAFT promotional
  - Launch materials for new drugs or new indications
  - Direct-to-consumer (DTC) broadcast ads
  - Non-launch materials
- Pre-submission required for certain drugs (e.g., Subpart H “accelerated approval”)

Surveillance

- Review materials submitted to OPDP at the

- Conferences
- Complaints
  - Healthcare professionals
  - Consumers
  - Lawyers
  - Competitors

Current OPDP Submissions

- 2253 submissions
  - Paper: 2 or 3 copies of paper submission
  - Electronic:
    - 2 or 3 copies of a CD-ROM that includes:
      - File titled 2253.pdf (2253 form)
      - File titled current.pdf in the main folder (current labeling)
      - File titled toc.pdf in the main folder (table of contents) with hypertext link to the content of the corresponding file

        Each promotional piece as an individual PDF file
      - Can also provide hypertext links to references
    - 2 or 3 copies of Paper 2253 form with signature

Current OPDP Submissions

- Request for Advisory for DTC TV ads
  - Cover letter
  - Generally 10 paper copies (17 copies if new drug or indication or drugs in a class advertised for the first time on TV) of:
    - Annotated storyboard (number frames)
    - Annotated approved product labeling (PI, PPI, Medication Guide)
    - Annotated references for product claims and disease/epidemiology claims
    - Spokesperson verification
    - Official Translation if the TV ad is in a foreign language
  - Optionally 2 copies of a video or animatic of the TV ad in an acceptable format

How to Submit TV Ad Proposals to OPDP

- Send each TV Ad proposal in as a

- Include a “OPDP” sticker or other prominent directional notation on the exterior of the package and on the cover letter itself
- Be sure your submission is “complete”

Acceptable Formats

  - MPEG-2-HD (High Definition Video)
  - WMV-HD (High Definition Video)
  - DVD-VR
  - DVD+VR
  - DVD-Video
  - Mini-DVD
  - CD-R and CD-RW
  - VHS
- Please Note: the following file formats are acceptable:
  - .iso files
  - Audio_ts/video_ts folders that include the following formats:
    - .bup
    - .ifo
    - .vob

Current OPDP Submissions

- Request for Advisory Comment on Proposed

  – 3 identical paper copies of:
    - Cover letter
      – List **all** promotional pieces included in the submission
        » Block format together at the beginning of the letter rather than spread throughout the letter
      – Include the identifying number and material type for each piece
      – Identify any priority piece(s) or an order or priority
    - Proposed annotated promotional materials
    - Annotated references
    - Annotated PI/PPI/Medication Guide

Tips for High Quality submissions

- For advisory submissions, notify OPDP that a submission is on the way
- Submit a *complete* official package
  - Email is not considered an official means of delivering a submission
  - Do not submit via FDA's electronic submission gateway
  - Send it to our ***central*** document room, not our physical address
  - Clearly indicate the submission is for OPDP
  - Separate submissions to DTC & HCP reviewers

Tips for High Quality submissions

- Check your submission for:
  - Clear view of the promotional piece
  - Clear view of the layout
    - Can you see all sides of 3-dimensional piece?
    - Can you see the entire spread?
  - Acceptable file format
    - Videos in a format FDA can view
    - NO .zip or .exe files

Administrative Issues

- Be forthcoming with your intentions
  - Please notify us ASAP if withdrawing a request for comments
  - Do not submit for advisory comments and go live with other promotional pieces that contain the same or similar claims
- Ensure media is labeled correctly and will play
  - Please see our website for acceptable options
  - Note that .exe and .zip files will be rejected
- Use the most current version of the PI in the submission and annotations

Updates

- OPDP has transitioned to a new tracking
- MA# has replaced MACMIS number

Electronic Submission Workgroup

- OPDP created an Electronic Submission Workgroup in 2008
  - March 2008 - Surveyed OPDP reviewers
  - May 2008 - Met with PhRMA EASE subgroup
  - September 2008 - Worked with PhRMA EASE subgroup to conduct an exercise that included a small number of test submissions over the ESG
  - November 2008 - Met with companies who participated in the exercise to have a dialogue about the reviewability of these pieces

Electronic Submission Workgroup

- Spring 2010: Larger scale exercise with Industry
- 2009 – 2011: Working on system, process, and eCTD issues that are necessary to move forward with the acceptance of electronic submissions over the ESG
- 2011 - OPDP has transitioned to a new tracking system (DARRTS) that will allow for the acceptance of electronic submissions in the future
- 2011 – new monitors for staff to assist in electronic review
- 2011 – draft Module 1 update released

What's Ahead

- eCTD
  - Draft update to module 1
    - Includes more granularity
    - Utilizes attributes (e.g. audience type, material doc type, material type)
    - Allows for identification of characteristics such as:
      - Professional vs consumer audience
      - Type of submission (e.g. advisory, 2253, accelerated approval presubmission)
      - Type of piece (e.g. TV ad, print ad, sales aid)

1.15 Promotional Section

- **1.15 *Promotional material <attribute = [promotional-material-audience-type]>***
  - 1.15.1 Correspondence relating to promotional materials
    - **1.15.1.1 Request for advisory comments on launch materials**
    - **1.15.1.2 Request for advisory comments on non-launch materials**
    - **1.15.1.3 Presubmission of launch promotional materials for accelerated approval products**
    - **1.15.1.4 Presubmission of non-launch promotional materials for accelerated approval products**
    - **1.15.1.5 Promotional materials submitted pursuant to section 503B**
    - **1.15.1.6 Response to untitled letter or warning letter**
    - **1.15.1.7 Response to information request**
    - **1.15.1.8 Correspondence accompanying materials previously missing or rejected**
    - **1.15.1.9 Withdrawal request**
    - **1.15.1.10 Submission of annotated references**
    - **1.15.1.11 General correspondence**
  - 1.15.2 Materials <attribute = [promotional-material-doc-type]>
    - **1.15.2.1 Material <attribute = promotional-material-type>**
      - 1.15.2.1.1 Clean version
      - 1.15.2.1.2 Annotated version
      - 1.15.2.1.3 Annotated labeling version
      - 1.15.2.1.4 Annotated references

Attributes

- Promotional Material Audience Type
  - Consumer
  - Professional
- Promotional Material Doc Type
  - Promotional 2253
  - Request for Advisory Launch
  - Request for Advisory Non-Launch
  - Presubmission Accelerated Launch
  - Presubmission Accelerated Non-launch
  - Promotional 503b

Attributes

- Promotional Material Type
  - Includes material types similar to the 2253 form (no 3 letter codes)
  - Includes additional material types not on the 2253 form
  - Designation of consumer vs professional already made with the promotional material audience attribute

Future Direction

- Implementation of updates to section 1.15 of Module 1
- Draft guidance development
- Finalize list of acceptable file formats
- Acceptance of promotional materials in eCTD format over the ESG
  - Currently not accepting electronic submission of any promotional materials over the ESG
  - Will be able to accept eCTD/ESG submissions after implementation of the eCTD M1 update

OPDP Contact Information

- Building 51 on White Oak Campus
  - Suites 3200 & 3300
- Fax Numbers
    - 301-847-8444
    - 301-847-8445
- Telephone Number
    - 301-796-1200
- Submission Address
  - Food and Drug Administration
    Center for Drug Evaluation and Research
    Office of Prescription Drug Promotion
    5901-B Ammendale Road
    Beltsville, MD 20705-1266